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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/027,439	02/20/98	PORTUGAL	F 044198.0000
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EXAMINER

SOUAYA, J

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 04/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/027,439

Applicant(s)

Portugal et al

Examiner

Jehanne Souaya

Group Art Unit

1655



☒ Responsive to communication(s) filed on Jan 22, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-36 is/are pending in the application.

Of the above, claim(s) 21-36 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Applicant's election of Group I, claims 1-20 is noted. Consequently, the claims currently being prosecuted on the merits are claims 1-20. Claims 21-36 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

1. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-18 are indefinite over the recitation of "an identifying nucleotide or identifying combination of nucleotides" because it is unclear what an identifying nucleotide is. For example, does it refer to a polymorphism in a particular sequence.

Claims 4-5, 7, 9-10, 14-16 are indefinite because it is unclear from the disclosure in the specification what each nucleotide position is actually being referred to in the sequence of Shigella. It is unclear, for example, where position 964 is, in other words, is where is it in the Shigella genome, and what does position "1" refer to? Is it the beginning of a gene?

Claim 19 is indefinite in the recitation of "a nucleic acid complementary" as it is unclear if this refers to the complement of SEQ ID NOS 3-6, or if it refers to a nucleic acid that is functionally complementary to the claims SEQ ID NOS. If the former is the case, applicant can overcome this rejection by stating instead "the complement".

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Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3-4, 6, 8, 11, 13 and 20 as rejected under 35 U.S.C. 102(a) as being anticipated by Cilia et al (Mol. Biol. Evol., vol. 13, pp 451-461, 1996) and accession number X80726.

The claims are drawn to nucleic acid molecules of 10-40 nucleotides that comprise nucleotides of 16s rRNA or rDNA of *Shigella* species but not of *E. Coli*. Accession number X80726 teaches a part of the *S. Sonnei* gene for 16s ribosomal DNA.

4. Claims 2, 12, and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Cilia et al and accession numbers X80723 and X80724.

The claims are drawn to nucleic acid molecules of 10-40 nucleotides that comprise nucleotides of 16s rRNA or rDNA of *E. Coli* species but not of *Shigella*. Accession number X80723 teaches sequences 71-100 of *E.coli* *rrnC* which will distinguish *E. Coli* from *Shigella*. Accession number X80724 teaches nucleotides 71-100 of an *Ecoli* 16s gene (ATCC 25922) which will distinguish *E. Coli* from *Shigella*.

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Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cilia et al or Hogan et al (US patent 5,714,321, 102(e) date is 2/24/94) in view of Faruque et al (J. Clinical Microbiology, 1992, vol. 30, pp 2996-2999).

The claims are drawn to nucleotide sequences of 10-40 nucleotides that comprise regions of the 16s ribosomal RNA or DNA sequences of Shigella species and E. Coli, wherein these sequences are capable of distinguishing Shigella from E.coli. Cilia et al teaches sequence heterogeneities among 16s RNA sequences of E. Coli and Shigella (see abstract, and figure 3) and teaches nucleotide differences among Eubacteria by showing a line up of regions from 16s genes

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across species levels, showing the nucleotide sequence similarities and differences. Hogan also teaches a method for preparing probes for use in qualitative and quantitative assays wherein the probes are capable of detecting and differentiating between eubacteria (see abstract). Hogan also teaches the hybridization of E. Coli probes to closely related organisms such as *Shigella boydii*, *Sh. flexneri*, *Sh. dysenteriae*, and *Sh. sonnei* (see col. 52, table 54). Faruque teaches studying restriction endonuclease restriction patterns of rRNA genes to distinguish between different strains of *sh. Flexneri*. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to construct the DNA sequences of the claimed invention for the use of probes and primers that could distinguish *Shigella* from *E. Coli*. Methods of distinguishing between different eubacteria using probes and primers that target regions of similarity and differences was readily known in the art at the time of the invention and is exemplified by the Hogan patent. The ordinary artisan would have been motivated to construct probes and primers of the claimed invention to identify and differentiate *E.coli* from *Shigella* as Cilia teaches how closely related the two genus of bacteria are (see Fig 1) and Faruque teaches that closely related sequences from strains of the same bacteria can be used to differentiate the different strains. As the sequences of the 16s rRNA and rDNA sequences of the *shigella* species and *E.coli* sequences were known at the time of the invention, it would have been obvious for the ordinary artisan to construct probes and primers to regions of variability to be able to differentiate the closely related bacteria. Such methods were readily known in the art as is shown by the large amount of

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literature available in the art that identifies regions of variability among closely related bacteria for the purpose of constructing probes and primers useful in methods of differentiation.

7. No claims are allowable.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Thursday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner

March 23, 2000

W. Gary Jones
W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600
3/27/00